PART A - OVERVIEW AND SUMMARY

PREAMBLE

This publication, Series 875 - Occupational and Residential Exposure Test Guidelines Group B - Postapplication Exposure Monitoring Test Guidelines [formerly Subdivision K of the Pesticide Assessment Guidelines (U.S. EPA, 1984)] provides guidance to persons required to submit postapplication exposure data under 40 CFR 158.390. Generally, such data are required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) when certain toxicity and exposure criteria have been met. The data are used to determine restricted-entry intervals for agricultural applications, postapplication entry restrictions at non-agricultural sites, or whether a pesticide could be used without appreciable postapplication risk in residential settings.

The postapplication exposure guidelines are being revised because the existing guidelines (i.e., Subdivision K) no longer meet the needs of persons required to submit postapplication exposure data under FIFRA. When the Subdivision K guidelines were first published in 1984, they were designed to establish an acceptable scientific approach to the postapplication (i.e., reentry, which is the entry into a site subsequent to pesticide application) data requirements for typical agricultural exposure scenarios. Since 1984, there have been a number of changes in the U.S. Environmental Protection Agency's (EPA's) data needs and requirements. First, as a result of the reregistration process[1], the Agency has been requiring more postapplication studies. These include both occupational and residential postapplication studies. Second, there is currently little guidance available on conducting residential postapplication studies, and standardized methods for assessing risk from pesticide use in the home are needed. Third, the revisions to the Good Laboratory Practice Standards in 1989 have focused more attention on quality assurance and quality control (QA/QC). The Rejection Rate Analysis (U.S. EPA, 1993) indicated that the most common cause for rejection of studies was inadequacy or lack of QA/QC.[2] Please note that the revised guidance will harmonize, to the extent possible, with guidance issued by international organizations such as the Organization for Economic and Cooperative Development (OECD).

[1]Reregistration is the Office of Pesticide Programs' process for reexamining supporting scientific data, reassessing human health and environmental risks, and making reregistration decisions for all pesticides initially registered before November 1, 1984.

[2]The Rejection Rate Analysis was undertaken to determine the reasons for study rejection and to help improve the acceptability rate of studies submitted for reregistration by pesticide registrants.

Initiatives to Generate Data

Two industry-wide proprietary Task Forces have been formed to share in the cost of developing generic exposure data to support pesticide product reregistrations in the United States, California, and Canada. Subject to further evaluation when data are completed, it is intended that the data generated by the Task Forces may also satisfy certain new product registration data requirements. The task force approach to fulfilling exposure data requirements has the potential to provide the Agency with a more complete and scientifically sound basis than is currently available for evaluating exposure at agricultural or residential use sites, including turf.

The *Agricultural Reentry Task Force (ARTF)* has been organized to develop a generic agricultural reentry exposure database intended to address agricultural postapplication and reentry data requirements for dermal and inhalation exposure (Guidelines 875.2400 and 875.2500). Proprietary studies will be evaluated for inclusion in the database, and data gaps will be identified in postapplication exposure data for agricultural uses. The ARTF will then conduct postapplication exposure studies and develop generic dermal transfer coefficients to cover hand labor activities for which insufficient data may exist.

The *Outdoor Residential Exposure Task Force (ORETF)* has been organized to develop exposure data for both professionals and non-professionals (residents) who mix, load, and apply pesticides to residential lawns or turf (Guidelines 875.1100 and 875.1300) and exposure data on non-professionals who reenter residential sites (grass lawn or turf) after pesticide application (Guidelines 875.2400 and 875.2500). As described above for the agricultural reentry database, existing published and proprietary studies will be evaluated for inclusion in the outdoor residential exposure database, and data gaps will be identified in both mixer/loader/applicator and postapplication exposure data for outdoor residential uses. The ORETF will then conduct mixer/loader/applicator and postapplication exposure studies and develop generic exposure data to support residential uses for which insufficient data may exist.

The proprietary generic agricultural and residential exposure data developed by the ARTF and the ORETF will be used in conjunction with product specific information (dislodgeable foliar residue data, toxicology data, etc.) to conduct risk assessments on a product-by-product basis, as needed.

A HISTORICAL PERSPECTIVE

Soon after the introduction of the organophosphorus (OP) insecticides in the late 1940s, specific toxic effects peculiar to some OP compounds were sometimes observed in field workers after applications of OP insecticides. These episodes were quite erratic; that is, the same pesticide might be used, at the same rate, on the same piece of ground, on the same crop for several years without any evidence of toxic effects, but in a

subsequent year, a number of field workers might experience symptoms characteristic of OP poisoning. This made it very difficult to investigate the problem and contributed to a number of misconceptions. Among these misconceptions were the ideas that only inhibitors (i.e., OP and carbamate insecticides) of the enzyme acetyl cholinesterase (AChE) cause reentry problems, that exposure primarily occurred by inhalation, and that only acute effects occurred (Popendorf and Leffingwell, 1982).

Because it was difficult to obtain information about the conditions leading to a reentry episode, it was difficult to arrive at a realistic model for the derivation of reentry intervals (reentry intervals are now known as restricted-entry intervals). Several models/methods were proposed, but prior to 1980 an "epidemiological" model was the primary method for the establishment of restricted-entry intervals. For example, in the June 25, 1975, Federal Register (Vol 40, no. 123, p. 26900), it was stated: "A number of sporadic episodes of acute adverse effects in field workers have been ascribed to toxic levels of pesticide residues on plant surfaces..... Establishment of reentry intervals for a specific pesticide-crop-cultural practice combination is currently conceived as a two-step process: (1) postulating a reentry interval; and (2) testing the postulated interval in the field." This approach was not satisfactory to the Agency. At a meeting of the FIFRA Scientific Advisory Panel (SAP) on February 22 and 23, 1980, the Agency presented a new model for the establishment of reentry levels and restricted-entry intervals. This "Allowable Exposure Level" (AEL) model obviated the epidemiological method. It allowed the establishment of reentry levels and intervals from toxicity and dissipation data through the use of a correlation of "dislodgeable residue" levels with exposure levels. This method addresses any class of compound and any mode of toxicity whether the effect is acute or chronic. It also makes it possible to establish reentry levels and intervals without the exposure of individuals to possibly hazardous pesticide residue levels. In this version of Series 875 Group B, the AEL concept has been modified and redefined as the Reentry Dose Level (RDL).

The 1980 guideline draft was revised in response to public comment and SAP advice, and was presented to the SAP again in May 1981. The 1981 draft was again revised, presented to, and reviewed by the SAP as part of the publication of several guideline sections. The final version of Subdivision K was published in October 1984. The data discussed in Subdivision K were then codified as data requirements at 40 CFR 158.140. This present document is a revision and expansion of the existing Subdivision K (i.e., U.S. EPA, 1984). These guidelines build on the previous version; for estimating the restricted-entry interval, and add new areas for data requirements.

EVIDENCE OF POSTAPPLICATION EXPOSURE

Agricultural

There is nationwide concern over postapplication exposure to pesticides, both in the agricultural and residential environments. Concerns from exposure to agricultural pesticides first began to be raised during the 1950s and 1960s as many of the environmentally persistent organochlorine insecticides (generally of low acute toxicity) began to be replaced with less persistent, but often acutely toxic, compounds. Among such chemicals are parathion and other cholinesterase-inhibiting organophosphates and N-methyl carbamates, including phosalone, dialifor, and methomyl. As this transition to more acutely toxic pesticides occurred, workers entering treated fields to cultivate or harvest crops were, on rare occasions, subjected to exposures at levels capable of producing illness or even death (CDFA, 1987; Milby et al., 1964; Lores, et al., 1978; Krook et al., 1971; Coye et al., 1986).

Over the past 20 years, these occupational safety concerns have led to the development of a number of State and Federal programs for farmworker protection, including establishment of restricted-entry intervals for acutely toxic pesticides and those suspected of teratogenic or carcinogenic potential. While these programs have undoubtedly contributed to a reduced occupational pesticide exposure, the concerns have not been eliminated, as evidenced by continuing documentation of exposure and injury even in States, such as California, which have comparatively advanced exposure and safety standards (Maddy et al., 1990).

EPA estimates that there are approximately 2.25 million agricultural workers nationwide. Of this population, roughly 10,000 to 20,000 may suffer from acute pesticide poisoning annually (U.S. EPA, 1992a). In California during 1990, a total of 1,919 occupationally-related possible, probable, or definite pesticide poisonings were reported to the California Department of Pesticide Regulation.[3] Of these cases, 165 (about 8 percent) can be attributed to field exposure. From 1982 to 1988, such cases rose from 274 to 492 reported annually (CDPR, 1993).

Maddy et al. (1990) describes three separate incidents during 1987 in the Central Valley of California where 78 field workers harvesting grapes developed moderate to severe cholinesterase depression. Forty-seven (~60 percent) reported symptoms compatible with cholinesterase poisoning. Fourteen workers were hospitalized for periods ranging from 1 to 7 days. In another incident (Napa Valley), nine workers developed signs and symptoms consistent with cholinesterase poisoning. From all evidence gathered, it appears that the insecticide phosalone was the cause in all four episodes (Maddy et al., 1990).

[3] Under State law (Section 2950 of the California Health and Safety Code), all California physicians are required to report any illness or injury suspected of having been caused by pesticide exposure.

Residential

Indoor Residential Exposure. Historically, concerns associated with the use of pesticides have focused primarily on agricultural environments. However, in recent years the use of pesticides in indoor and residential environments has escalated, initiating a cause for increased attention to pesticide exposures in these environments.

It is estimated that over 90 percent of United States households use a variety of pesticide products from antimicrobial disinfectants to insecticides (Godish, 1985). Research Triangle Institute (RTI, 1992) estimates that in 1990 about 20 percent of all households (about 16 million households) had their homes commercially treated for indoor pests such as cockroaches, ants, or fleas. This large percentage of pesticide usage warrants attention because most individuals spend a significant period of time indoors. It is estimated that on a daily basis an employed adult spends about 15 hours per day at home and a small child spends about 21 hours per day at home (Lewis, 1990).

According to the National Center for Health Statistics (NCHS, 1982-1991), residential pesticide poisoning resulted in 97 accidental deaths between 1980 and 1988. This accounts for approximately 77 percent of the pesticide deaths for which location was specified. Between 1981 and 1990, an annual average of 20,000 pesticide exposures were reported to emergency rooms throughout the United States (Blondell, 1990). Approximately 82 percent of these reportedly occurred in the home.

Another concern has been expressed about exposures to preservatives (i.e., antimicrobials) found indoors. Antimicrobial pesticides are used indoors to treat surfaces/areas/objects including, but not limited to, carpets, hard surfaces, floors, tables, laundry, mattresses, plastic products, etc. Another consideration is the exposure to volatile pesticide compounds contained in products used indoors (i.e., preservatives used in paints) for varying periods of time.

As a result of increased concern and lack of knowledge regarding the residential use of pesticides, EPA conducted the Nonoccupational Pesticide Exposure Study (NOPES), which measured residents' exposure to 32 pesticides. The study demonstrated that air levels of many pesticides were significantly higher indoors than outdoors (U.S. EPA, 1990). Currently, EPA is conducting the National Human Exposure Assessment Survey (NHEXAS), which will measure pollutant concentrations, including pesticides, in air, water, soil, dust, food, surfaces, and human tissues using various sampling techniques (Sexton et al., 1995a, 1995b). The survey will also collect human activity and population characteristic data via questionnaire. Some of the objectives of NHEXAS are to document the occurrence, distribution, and determinants of total exposure in the general population, monitor geographic and temporal trends in exposure, and evaluate factors that contribute to total exposure (Lebowitz et al., 1995).

Outdoor Residential Exposure. Each year, approximately 70 million pounds of pesticide active ingredients are used in the home and garden (LCPAC, 1993; GAO, 1993). According to the National Home and Garden Pesticide Use Survey (RTI, 1992), approximately 18 million households use pesticides on lawns, 8 million use pesticides on food crops, and 14 million use pesticides on ornamental plants. Approximately 15 percent of the 66.8 million households with private lawns have pesticides applied by someone other than the household member (i.e., a commercial lawn care company) (RTI, 1992). These statistics have generated considerable public concern over potential exposure and health effects, especially for children entering recently treated areas.

Outdoor-applied pesticides may also be tracked or transported indoors where they become a secondary source of exposure to the building occupants. Secondary sources of indoor exposures may occur from homeowner or commercially-applied lawn products (herbicides, insecticides, and fungicides); garden pesticides; agricultural or community spray drift; and fungicide-treated lumber. Transfer of lawn pesticides to indoor carpets by foot traffic was experimentally demonstrated by Nishioka et al. (1996). Pesticides are also used on playground equipment and in swimming pools (i.e., biocides) to which children may potentially be exposed (i.e., work clothing washed with other clothing, children touching contaminated clothing, etc.).

Children's Exposure. As a follow-up to the NOPES Study, EPA conducted a study to evaluate monitoring methods that may be used to assess potential exposures of children to pesticides found in the home environment. The study suggested that pesticides in household dust and yard soils may represent a source of exposure among infants and children. The study sampled homes that were not specifically treated with pesticides for the purposes of the study, but were surveyed to determine pesticide exposure as a result of actual pesticide usages in the home and yard. Preliminary results indicated that a variety of pesticides were detected in house dust. The most prevalent were the older, persistent chlorinated hydrocarbons such as dieldrin, chlordane, and pentachlorophenol that were also frequently detected in NOPES (Lewis et al., 1994).[4]

Residential exposure to pesticides has been associated with a significant number of reported pesticide poisoning incidents involving children (Fenske et al., 1990; Berteau et al., 1989; Zweiner and Ginsburg, 1988). Zweiner and Ginsburg (1988) reported on organophosphate and carbamate poisonings among 37 infants and children in Texas. Fifteen percent of the children showed symptoms within 36 hours after their home had been sprayed or fogged with insecticide. One infant showed signs of organophosphate poisoning after sleeping on a treated carpet. Data collected from Poison Control Centers in 1992 indicated that nearly 63,000 exposures to pesticides (including disinfectants) had occurred in children under the age of 6 years (Litovitz and Holm, 1993).

[4]It should be noted that most uses of dieldrin, chlordane, and pentachlorophenol have been canceled.

Fenske et al. (1990) measured chlorpyrifos concentrations in a carpeted apartment following treatment and found that the chlorpyrifos vapors measured in the infant's breathing zone (25 cm above the carpet) were significantly higher than in the sitting adult's breathing zone. It was suggested that although open windows provided dilution of air 1 m above the carpet, the treated carpet was a source of volatilized chlorpyrifos and concentrations near the floor were not as diluted (Fenske et al., 1990). Infants and toddlers may come into contact with these residues when crawling or playing on the floor.

LEGISLATIVE AUTHORITY

Legislative Basis

FIFRA provides a statutory framework under which EPA, primarily through a registration process, regulates the sale, distribution, use, and disposal of pesticides. As the standard for registration of a pesticide, FIFRA requires that the pesticide, when used in accordance with widespread and commonly recognized practices, will not cause unreasonable adverse effects on human health or the environment (7 U.S.C. section 136a(c)(5) and (7)). A similar standard applies to the reregistration of existing pesticide products and Agency approval of experimental use of unregistered pesticides (7 U.S.C. sections 136b(g)(2) and 136c). FIFRA defines "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide" (7 U.S.C. section 136b(b)).

For the Agency to make well-informed "unreasonable adverse effects" determinations, FIFRA gives EPA broad authority, before and after registration, to require specific testing by registrants and/or applicants and submission of the resulting data to the Agency (7 U.S.C. sections 136 a, b, and c). Registrants and/or applicants are under a continuing obligation to provide the Agency with adequate information about their products to demonstrate that the products meet the statutory standard for registrability and to report any additional information that may affect the Agency's determination (7 U.S.C. sections 136a(c)(2)(B), 136b(b), and 136d(a)(2)).

Recently, the Food Quality Protection Act (FQPA) of 1996 was enacted. FQPA has amended FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) to provide a comprehensive and protective regulatory scheme for pesticides. According to the U.S. EPA (1996), the new law mandates "a single, health-based standard for all pesticides in foods; provides special protections for infants and children; expedites approval of safer pesticides; creates incentives for the development and maintenance of effective crop protection tools for American farmers; and requires periodic re-evaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticide registrations will remain up to date in the

future." The law also has special provisions for minor use pesticides and antimicrobials, and will require that aggregate risks be evaluated.

EPA's Role in Providing Guidance

The Data Requirements for Registration (40 CFR 158) specify the types of data and information generally required to make sound regulatory judgements under FIFRA for each pesticide proposed for experimental use, registration, amended registration, or reregistration with respect to its potential for causing unreasonable adverse effects.

In 1983, guidelines were issued as a series of documents titled the "Pesticide Assessment Guidelines." The Guidelines describe acceptable protocols, test conditions, and the data that must be reported for each test requirement. The data requirements are intended to generate data and information pertaining to the identity, composition, potential adverse effects, and environmental fate of pesticides. The Guidelines were set forth as separate Subdivisions as follows:

- Subdivision D (Product Chemistry);
- Subdivision E (Wildlife and Aquatic Organisms);
- Subdivision F (Hazard Evaluation: Human and Domestic Animals);
- Subdivision G (Product Performance);
- Subdivision I (Experimental Use Permits);
- Subdivision J (Hazard Evaluation: Nontarget Plants);
- Subdivision K (Reentry Exposure);
- Subdivision L (Hazard Evaluation: Nontarget Insects);
- Subdivision M (Biorational Pesticides (since revised under the title "Microbial and Biochemical Pest Control Agents");
- Subdivision N (Chemistry: Environmental Fate);
- Subdivision O (Residue Chemistry); and
- Subdivision R Spray Drift.

Since 1987, a new Guideline document, Subdivision U: Applicator Exposure Monitoring, has been published. In addition, several position documents and addenda to the guidelines have been published.

Currently, the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) is harmonizing its pesticide and toxics guidance (i.e., the "Pesticide Assessment Guidelines") with similar international guidance such as that issued by OECD. The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data

requirements of EPA under TSCA (15 U.S.C. 2601) and FIFRA (7 U.S.C. 136, *et seq*.). A goal of guideline harmonization is to reduce the data collection burden on industry as the results of a study conducted following harmonized guidelines may be used by a number of regulatory organizations/countries. In addition, harmonizing OPPTS Guidelines with those of the OECD will enable the Agency to achieve compliance with the OECD's Mutual Acceptance of Data Doctrine.

The harmonized OPPTS Test Guidelines are arranged into ten series as follows, each of which is broken down into a number of Groups:

- Series 810 - Product Performance Test Guidelines;
- Series 830 - Product Properties Test Guidelines;
- Series 835 - Fate, Transport, and Transformation Test Guidelines;
- Series 840 - Fate and Transport Field Studies Test Guidelines;
- Series 850 - Ecological Effects Test Guidelines;
- Series 860 - Residue Chemistry Test Guidelines;
- Series 870 - Health Effects Test Guidelines;
- **Series 875 - Occupational and Residential Exposure Test Guidelines**
  - Group A - Applicator Exposure Monitoring Test Guidelines (i.e., the existing Subdivision U Guidelines)
  - **Group B - Postapplication Exposure Monitoring Test Guidelines**;
- Series 880 - Biochemicals Test Guidelines; and
- Series 885 - Microbial Pesticide Test Guidelines.

The guidance being drafted in this document is Group B of Series 875 which includes a revision of the former Pesticide Assessment Guidelines - Subdivision K. Table A-1 depicts each of the Series 875, Group B Guidelines along with their former Subdivision K Guideline numbers (i.e., Series 130).

Please note that the QA/QC guidance in this document (i.e., Part C) should be used by investigators who are doing either Applicator Exposure Monitoring Studies or Postapplication Exposure Monitoring Studies.

REGULATIONS AND POLICIES

In conducting postapplication exposure monitoring studies, the study investigator needs to be cognizant of certain Agency regulations and policies that could impact investigation. For instance, research being conducted on human subjects must conform to the requirements of the "Common Rule." Further, investigations must be carried out following the requirements of the Good Laboratory Practices (GLPs) (40

CFR 160) and must comply with the requirements of the Worker Protection Standards (WPS) (40 CFR 156 and 170) and any labeled safety requirements, including those for products that are out of the scope of the WPS. Highlighted below are Agency regulations and policies that a study investigator must consider in pursuing postapplication exposure monitoring.

TABLE A-1. Postapplication Exposure Monitoring Guideline Numbers

GUIDELINE	SERIES 875 NUMBER	SUBDIVISION K NUMBER
Background and General Provisions	875.2000	130-1
Study Design	875.2000	Not included
Dislodgeable Foliar Residue Dissipation: Agricultural	875.2100	132-1
Transferable Residue Dissipation: Lawn and Turf	875.2100	Not included
Soil Residue Dissipation	875.2200	132-2
Indoor Surface Residue Dissipation	875.2300	Not included
Dermal Exposure	875.2400	133-3
Inhalation Exposure	875.2500	133-4
Biological Monitoring	875.2600	Not included
Product Use Information	875.2700	Not included
Descriptions of Human Activity	875.2800	133-1
Data Reporting and Calculations	875.2900	134

Protection of Human Subjects

Common Rule. The Federal Government has established common requirements for the protection of human subjects involved in research conducted or funded by a number of Federal Departments and Agencies including EPA and United States Department of Agriculture (USDA) (U.S. EPA, 1991). These requirements are known informally as "the common rule." EPA has adopted the common rule as regulations; they are codified at 40 CFR 26. The Agency is now drafting an order (EPA Order 1000.17 Human Subject Research) for implementing the policy set forth at 40 CFR 26.

FIFRA. In addition to the common rule, FIFRA also provides requirements for the protection of human subjects. Pursuant to FIFRA section 12(a)(2)(P), it shall be unlawful for any person "to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test."

Worker Protection Standard. On August 21, 1992, EPA published the Worker Protection Standard Final Rule under the authority of FIFRA (U.S. EPA, 1992b). These regulations (codified at 40 CFR 156 and 170) were promulgated for the protection of workers from agricultural pesticides. The provisions of the Worker Protection Standard are directed toward the working conditions of two types of employees: those who handle agricultural pesticides (e.g., mix, load, apply, clean or repair equipment, act as flaggers, etc.) and those who perform tasks related to the cultivation and harvesting of plants on farms or in greenhouses, nurseries, or forests that may have been treated with pesticides (e.g., scouting, irrigation workers, and harvesters). The Worker Protection Standard includes provisions intended to: (1) eliminate or reduce exposure to pesticides; (2) mitigate exposures that occur; and (3) inform employees about the hazards of pesticides.

In conducting any field study, the investigator must ensure that the applicable provisions of the Worker Protection Standard regulations are being fulfilled. Generally, hazard information must be available for all workers, appropriate protective clothing must be provided, and decontamination sites and emergency assistance must be available. See Part C (QA/QC) for specific guidance on protecting human subjects involved in postapplication monitoring studies.

Good Laboratory Practices

The FIFRA Good Laboratory Practice (GLP) Standards are regulations that were promulgated to ensure the quality and integrity of data submitted to the Agency (U.S. EPA, 1989). "EPA originally published FIFRA GLP standards in the **Federal Register** of November 29, 1983 (48 FR 53946), which were codified at 40 CFR part 160....These regulations were promulgated in response to investigations by EPA and FDA during the mid-1970s that revealed that some [toxicological] studies had not been conducted in accordance with acceptable laboratory practices" (U.S. EPA, 1989). In 1989, EPA revised the GLPs to: (1) include the environmental testing provisions currently found in the TSCA GLP standards and; (2) apply to all data submitted to support registration/reregistration/special review of pesticides under FIFRA. "In summary, the FIFRA GLP standards will allow EPA to ensure the quality and integrity of all data submitted in support of pesticide product research or marketing permits" (U.S. EPA, 1989). Part C of this document (Quality Assurance/Quality Control) provides a detailed explanation of how to comply with the FIFRA GLPs.

GUIDELINE REQUIREMENTS -- AN OVERVIEW

EPA requires pesticide postapplication exposure data when it needs to determine: (1) a restricted-entry interval (i.e., the length of time required before persons could enter a pesticide-treated site without appreciable risk); or (2) if a pesticide could be used without appreciable risk in a residential setting. Generally, these data are required for highly toxic pesticides that have use types likely to result in significant

dermal and inhalation exposure to persons entering treated fields or treated homes. The decision to require postapplication exposure data is made by examining the toxicity and exposure criteria detailed at 40 CFR 158.390.

At a minimum, dissipation, exposure, and toxicity data are needed to determine a restricted-entry interval and/or to assess risk. Dissipation may occur on foliage, soil, or indoor surfaces. The Agency may require one or more of the following studies to determine the dissipation rate, depending on the use of the pesticide: Dislodgeable or Transferable Foliar Residue (DFR) Dissipation Study; Soil Residue Dissipation (SRD) Study; or an Indoor Surface Residue (ISR) Dissipation Study. Guidelines for assessing dissipation are presented in Part B - Chapters 3, 4, 5, and 6. Exposure may occur via the dermal, inhalation, or nondietary ingestion routes. To determine human exposure, EPA may require Dermal Exposure (Part B - Chapter 7) or Inhalation Exposure (Part B - Chapter 8) studies. Nondietary ingestion exposure may be assessed using the guidance provided in Part B - Chapter 9. Alternatively, study investigators may choose to determine human exposure through Biological Monitoring (Part B - Chapter 10). Toxicity data are needed in conjunction with the dissipation and exposure data to estimate the restricted-entry interval or to ensure no appreciable risk from use in residential settings. No new toxicological studies are required under 40 CFR 158.390. Rather, the toxicological data needed are derived from studies required under 40 CFR 158.340. These data requirements are described in Subdivision F: Hazard Evaluation - Human and Domestic Animals. Finally, estimates may be refined by submitting dermal absorption data, product use information (Part B - Chapter 11), and descriptions of human activity (Part B - Chapter 12). Such information will allow the Agency to avoid using "worst-case" estimates. The types of studies that may be required are described in Table A-2. Selecting the types of studies required for estimating postapplication exposure is dependent upon the pesticide site and use patterns, potentially exposed populations, significant exposure routes, and the duration over which exposure occurs.

USE OF THE GUIDELINES

The information provided in this Background section is intended to provide the reader with an understanding of why postapplication data are required and how to determine which studies need to be performed. The next sections of this document -- Part B - Guidelines, Part C - QA/QC, and Part D - Exposure and Risk Assessment -- provide the actual "how-to" guidance on conducting and implementing postapplication exposure studies.

Each "Guideline" in Part B is labeled by an 875 number. This is in keeping with the OPPTS initiative to develop harmonized guidelines and numbering, as described earlier in this Background section. In addition to the Guideline of interest (e.g., Guideline 875.2500 - Inhalation Exposure), the study

investigator must at a minimum also consult Guideline 875.2000 - Background/Study Design, Part C - QA/QC, and Part D - Exposure and Risk Assessment/Calculations.

TABLE A-2. Description of Required Studies

Study	Description
Dissipation Studies	
Dislodgeable Foliar Residue (DFR) Dissipation Study (Agricultural) or Transferable Residue Dissipation Study (Lawn and Turf) Guideline 875.2100	DFR studies and transferable residue studies assess the dissipation rate of pesticides that can be dislodged and transferred from foliar surfaces (e.g., leaves of plants, turf, and garden plants) to human skin by analyzing foliar samples collected at various postapplication time intervals.
Soil Residue Dissipation (SRD) Study Guideline 875.2200	SRD studies assess the dissipation of pesticide residues in soil by extracting and measuring residues in soil collected at specified intervals postapplication.
Indoor Surface Residue (ISR) Dissipation Study Guideline 875.2300	ISR studies characterize dissipation of transferable pesticide residues from indoor surfaces as a function of time by sampling and analyzing surface residues at various time intervals following application.
Measurement of Human Exposure	
Dermal Exposure Guideline 875.2400	Passive dosimetry studies assess potential dermal exposure to humans by analyzing pesticide residues on dosimetry patches or clothing worn by study participants during reentry activities.
Inhalation Exposure Guideline 875.2500	Inhalation monitoring studies establish potential inhalation levels during postapplication activities by analyzing air samples collected via personal sampling pumps, passive monitors, high-volume samplers, or other techniques.
Nondietary Ingestion Exposure Assessment	Nondietary ingestion exposure may be estimated using residue data collected under one of the dissipation study guidelines above, and standard ingestion rates based on the age group or activity of interest.
Biological Monitoring Guideline 875.2600	Biological monitoring assesses internal dose by measuring either body burden or enzyme activity in selected tissues or fluid, or from the amount of pesticide or its metabolites eliminated from the body.
Other Data	
Product Use Information Guideline 875. 2700	The submission of product use information (e.g., typical use of the pesticide such as pounds applied) and its associated cultural practices allow more precise evaluation of exposure.
Descriptions of Human Activity Guideline 875.2800	Human activity data define the activity patterns that affect exposures. These data include site-specific and test subject-specific information.

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